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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,889	11/07/2001	Robert D. Black	9099-4	7939
20792	7590	07/07/2005	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/005,889

Applicant(s)

BLACK, ROBERT D.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-17 and 29-42 is/are pending in the application.
- 4a) Of the above claim(s) 38-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-17 and 29-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of the claims**

The Request for Continued Examination and the amendment filed May 12, 2005 is acknowledged and has been entered.

### ***Election/Restrictions***

1. Newly submitted claims 38-42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 38 and 39 require a second in vivo optical radiation detector configured to detect second optical radiation emitted by excited labeled binding molecules and the originally presented claims do not require this limitation.

Claim 40 requires an in vivo optical radiation source and an in vivo optical radiation detector and originally presented claims do not require these limitations.

Claim 40 also requires binding molecules for binding with biomolecules associated with tumors and the originally presented claims do not require this limitation.

Claim 41 and 42 require an apparatus configured to controllably release labeled binding molecules for excitation and the originally presented claims do not require this limitation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38, 39, 41 and 42 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-17, 29-37 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is vague and indefinite because it is unclear how the processor circuit is configured to operate in conjunction with the release of labeled binding molecules. Is the processor circuit used to detect labeled molecules? Is the processor circuit coupled to something else to release molecules? It is unclear what applicant intends.

Claim 33 the recitation "configured to active" is vague and indefinite. It is unclear what applicant intends.

Claim 37 the recitation "out of phase with" is vague and indefinite. It is unclear what applicant intends.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Art Unit: 1641

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovacs et al (US 5,833,603).

Kovacs et al disclose a circuit comprising Light emitting diodes (LED's) (optical radiation source), a photosensor (optical radiation detector) and control circuitry (col 5, lines 1-27, col 11, line 44 – col 12, line 33). Kovacs et al disclose that this circuit can be configured for in vivo detection. Kovacs et al disclose that the photosensor can be photodiodes or phototransistors (col 2, lines 25-30).

With respect to the recitation "optical radiation emitted by excited labeled binding molecules" as recited in the instant claims. Since Kovacs et al teach the same circuit as recited, the circuit of Kovacs is capable of detecting excited labeled binding molecules and therefore, Kovacs anticipates the claims.

With respect to the recitations "for in vivo use that emits first optical radiation", "for in vivo use that detects second optical radiation emitted by excited labeled binding molecules" and "for excitation by the first optical radiation" these recitations are intended use of the circuit and a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, Kovacs et al reads on the instantly recited claims.

6. Claims 8, 15-17 and 29-34, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Santini, Jr. et al (US 6,551,838).

Art Unit: 1641

Santini, Jr. et al. disclose a circuit for in vivo applications. Santini, Jr. et al. disclose the circuit comprises a fiber optic which emits light (optical radiation source). Santini, Jr. et al also discloses that the fiber optic can detect and measures changes (optical radiation detector) in fluorescence or some other optical phenomenon. Santini, Jr. et al disclose control circuitry coupled to the fiber optic (col 9, lines 54-67, col 15, line 59 – col 16, line 43 and Figure 7). Santini, Jr. et al disclose coating or encapsulating all components of the circuit in a biocompatible material such as polyethylene glycol or metal or ceramic (col 9, lines 47-51 and col 15, lines 47-51). Santini, Jr. et al disclose the circuit is on a backing plate (platform) (col 17). Santini, Jr. et al disclose the device can be the size of a millimeter (col 4, lines 35-36).

With respect to the recitation “optical radiation emitted by excited labeled binding molecules” as recited in the instant claims. Since Santini, Jr. et al teach the same circuit as recited, the circuit of Santini, Jr. et al is capable of detecting excited labeled binding molecules and therefore, Santini, Jr. et al anticipates the claims.

With respect to the recitations “for in vivo use that emits first optical radiation”, “for in vivo use that detects second optical radiation emitted by excited labeled binding molecules” and “for excitation by the first optical radiation” these recitations are intended use of the circuit and a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, Santini Jr. et al reads on the instantly recited claims.

Art Unit: 1641

With respect to 29-34, 36 and 37 since Santini Jr. et al disclose the same structures as recited in the instant claims and since Applicant has not recited any structural differences over Santini Jr. et al. The circuit of Santini Jr. et al is capable of performing the limitations of the recited claims and therefore, Santini Jr. et al anticipates the claims.

7. Claims 8, 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Crowley (US 6,343,227).

Crowley teaches a circuit comprising a light source (optical radiation source) and a light detector (optical radiation detector). Crowley teaches that the light source illuminates a substance and the detectors detect optical properties of the illuminated substance by measuring modified light signals (col 2, lines 18-31) (Figure 1A). Crowley teaches the circuit comprises a modulator for modulating the light source and also comprises an analog to digital converter and a microprocessor for spectral analysis (col 3, lines 34-57). Crowley teaches the light source may be a light emitting diode and the light detector may be a photodiode (col 2, lines 44-50). Crowley teaches the light source may be coupled to a filter (col 9, lines 8-11). Crowley teaches the light detector may be coupled to a filter (col 5, lines 20-48, Fig. 2A and Fig. 4).

With respect to the first frequency is greater than the second frequency as recited in the instant claims. This limitation depends on the label that is used, and the label is not part of the circuit and therefore, whether or not the first frequency is greater than the second frequency is irrelevant. Therefore, Crowley anticipates the instantly recited claims.

With respect to the recitations "for in vivo use that emits first optical radiation", "for in vivo use that detects second optical radiation emitted by excited labeled binding molecules" and "for excitation by the first optical radiation" these recitations are intended use of the circuit and a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, Kovacs et al reads on the instantly recited claims.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.



Art Unit: 1641

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini Jr. et al. (US 6,551,838) in view of Gazdzinski (US 2001/0051766) or Meyer et al (US 6,217,869).

See above for the teachings of Santini Jr. et al.

Santini Jr. et al differ from the instant invention in failing to specifically teach the optical radiation source comprises a laser.

Gazdzinski et al disclose a laser coupled to a fiber optic (page 14, paragraph 0177, Fig. 11). Gazdzinski et al disclose that this provides for the transmission of light energy in an efficient manner (paragraph 0177).

Meyer et al disclose a fiber optic coupled to a laser (col 49, lines 19-25). Meyer et al disclose that this provides for the precise delivery of light.

It would have been obvious to one of ordinary skill in the art to incorporate a laser as taught by Gazdzinski et al into the device of Santini Jr. et al because it is well known in the art to couple fiber optics with lasers and further because Gazdzinski et al shows that this provides for the transmission of light energy in an efficient manner.

It would have also been obvious to one of ordinary skill in the art to incorporate a laser as taught by Meyer et al into the device of Santini Jr. et al because it is well known in the art to couple fiber optics with lasers and further because Meyer teaches that this provides for the precise delivery of light.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini Jr. et al in view of Sheppard, Jr. et al (US 2002/0072784).

See above for teachings of Santini Jr. et al.

Santini Jr. et al differ from the instant invention in failing to teach an inductor coupled to the processor (page 5, paragraph 0055 and Figure 1).

Sheppard Jr. et al. disclose an inductor coupled to a processor. Sheppard Jr. et al discloses that this inductor provides for devices, systems and methods for wirelessly powering and/or communicating with microchip devices used for the controlled exposure and release of reservoir contents (abstract). Sheppard Jr. et al also teaches that this provides for devices for reducing or eliminating the need for pre-charged power sources and provides avoiding explantation of implanted microchip devices for the purpose of replacing or recharging the devices power source or for the purpose of reprogramming the devices' microprocessor and also provides additional means for powering and communicating with microchip devices (page 1, paragraphs 0007-0009).

It would have been obvious to one of ordinary skill in the art to incorporate an inductor such as taught by Sheppard Jr. et al into the processor of Santini Jr. et al because Sheppard Jr. et al teaches that this inductor provides for devices, systems and methods for wirelessly powering and/or communicating with microchip devices used for the controlled exposure and release of reservoir contents (same type of device as disclosed in Santini Jr. et al.) and further because Sheppard Jr. et al also teaches that this provides for devices for reducing or eliminating the need for pre-charged power sources and provides avoiding explantation of implanted microchip devices for the purpose of replacing or recharging the devices power source or for the purpose of reprogramming the devices' microprocessor and also provides additional means for powering and communicating with microchip devices.

12. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini, Jr. et al (US 6,551,838) in view of Santini Jr. et al (US 6,491,666).

See above for the teachings of Santini Jr. et al (US 6,551,838).

Santini Jr. et al (US 6,551,838) differs from the instant invention in failing to specifically teach a piezoelectric circuit responsive to the processor circuit, wherein the piezoelectric circuit is configured to vibrate under control of the processor circuit to release the labeled binding molecules.

Santini Jr. et al (US 6,491,666) disclose microfabricated devices for the release of molecules. Santini Jr. et al (US 6,491,666) disclose piezoelectric elements such as a thin film of piezoelectric material that form a barrier layer. Santini Jr. et al (US 6,491,666) disclose that actuation of this piezoelectric material is achieved by components located on the device that generate ultrasonic energy (col 12, lines 11-47). Therefore, Santini Jr. et al (US 6,491,666) disclose a piezoelectric circuit. Santini Jr. et al (US 6,491,666) disclose that these components are activated by control circuitry (col 3). Santini Jr. et al (US 6,491,666) disclose that this provides for an alternative active release device (col 12) and also provides for accurate and reliable delivery of molecules (col 1).

It would have been obvious to incorporate piezoelectric elements and components as taught by Santini Jr. et al (US 6,491,666) into the device of Santini Jr. et al (US 6,551,838) because Santini Jr. et al (US 6,551,838) specifically teaches that the barrier layer is responsive to a stimulus (col 8, lines 53-57) and Santini Jr. et al (US 6,491,666) teaches that this provides for disintegration of a barrier layer and also this provides for an alternative active

Art Unit: 1641

release device which provides for accurate and reliable delivery of molecules. Therefore one of ordinary skill in the art would have a reasonable expectation of success incorporating piezoelectric elements and components as taught by Santini Jr. et al (US 6,491,666) into the device of Santini Jr. et al (US 6,551,838).

**Conclusion**

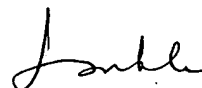
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art Unit 1641  
June 29, 2005



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